

### **REMARKS**

The present Request for Continued Examination, along with amended and new claims and arguments, are being submitted in response to the Office action dated December 20, 2002. Claims 8-15 were pending in the application. According to the Office action, claims 8-14 were withdrawn from consideration by the Examiner and claim 15 was rejected. By the present correspondence, claim 15 has been amended and claims 16-24 have been added. Reconsideration is respectfully requested in light of the amendments being made hereby and of the following remarks. Applicant wishes to point out that claim 16 is based on former claim 12; 17 on former claim 1 and the specification (p. 7, lines 5-13; Fig. 1; example 1); claim 18 on former claim 12; claim 19 on former claim 12 (and is further supported in the specification (p. 7, 2<sup>nd</sup> paragraph)); claim 20 on former claims 2 and 9; claim 21 to former claims 4 and 10; claim 22 on former claims 3 and 11; claim 23 on former claims 5, 8 and 12; claim 24 on former claim 13 and claim 25 on present claim 15 and is further supported by the specification at page 2, lines 1-4 and page 9, lines 18-19.

### **Rejection of Claim 15 under 35 U.S.C. 102(b)**

Claim 15 has been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,580,573 (Kydonieus et al.). The Examiner states that Kydonieus et al. teaches a temperature controlled polymeric device and that the device is used for topical application. Additionally, the Examiner states that the device can be constructed in three types, one being a combined monolithic reservoir. With this system, the Examiner explains that a rate-controlling polymer encapsulates the active-polymer layer and that the rate-controlling layer

has a glass transition temperature in the range of 20 to 50 degrees Celsius. The non-rate controlling polymer containing the active agent has a low glass transition temperature and the polymer components of the device have high molecular weights.

Applicant respectfully submits that claim 15, as amended, and the subsequent new claims, are not anticipated by Kydonieus et al. Kydonieus et al. discloses a tri-layer system (Fig. 3 and col. 2, line 39 to col. 4, line 54) in which the active substance is dispersed in an intermediate layer ("polymer matrix"). The glass transition temperature of the polymer of this matrix layer is "significantly below the use temperature" (col. 2, lines 63-77), which is in the range of 20-50°C (col. 2, lines 53-55). In contrast, the outer layers encapsulating the active substance matrix are made up of a rate-controlling polymer having a glass transition temperature which is greater than the storage (or use) temperature (col. 2, lines 66 to col. 3, line 4; col. 2, lines 39-43; and claim 1). Therefore, in the tri-layer system described in Kydonieus et al., the polymers used for making the intermediate layer have a glass transition temperature which is lower than the glass transition temperature of the encapsulating layers.

Applicant points out that this is the opposite of what is claimed by the present invention in claims 15 as amended and new claims 16-24, wherein  $T_g2$  is greater than  $T_g1$  (see claims 15, 17 and 23). Therefore, Applicant submits that Kydonieus et al. does not teach or disclose each and every feature of the present claims and respectfully submits that it does not anticipate the claims of the present application.

The Examiner has also rejected claim 15 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,023,084 (Chien et al.). The Examiner states that Chien et al. discloses a transdermal system containing a backing layer, a polymer layer and an adhesive layer. In

addition, the Examiner states that the first layer contains an active agent and a polyacrylic adhesive or reservoir layer, the second layer contains polyisobutylene polymer, or high molecular weight polymer and the third layer contains polyacrylic adhesive and an active agent. Further, example 8 teaches laminating the polymer layers. In addition, the Examiner states that the active agent is administered in a controlled manner and that the reference teaches the method of estrogen therapy by placing the system on the skin of a subject.

The Applicant respectfully submits that Chien et al. discloses a transdermal drug delivery system having a tri-layer structure comprising a polymer layer, and adhesive layer and a "separating layer" interposed therebetween (example 8, col. 21). The aforementioned polymer layer and adhesive layer may be referred to as the first and third layers, respectively, of the present invention. Accordingly, the separating layer of Chien et al. would correspond to the second layer of the present invention.

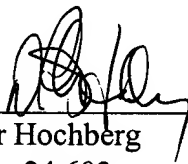
As the Examiner has pointed out, the separating layer is made of polyisobutylene, in particular Oppanol B 80 (col. 13, lines 20-21). This is a rubber-like polymer (Exhibit A) which has a glass transition temperature in the range of  $-60$  to  $-74$  C° (Exhibit B, where "PIB" denotes polyisobutylene). Referring to page 3, lines 18-32 of the present specification, these polyisobutylene polymers are "in the soft rubber-like state." According to Example 8 of Chien et al., a polyacrylic adhesive is used for making both the polymer and the adhesive layer. While it is true that the glass transition temperature of the polymer of the separating layer is different from the glass transition temperatures of the polymer layer and the adhesive layer, Chien et al. does not teach or disclose any type of intermediate layer containing a polymer which has a higher glass transition temperature relative to that of the polymer of

either the first or third layers.

**Conclusion**

For the foregoing reasons, it is believed that the present application as amended is in condition for allowance, and such action is earnestly solicited. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

By:   
D. Peter Hochberg  
Reg. No. 24,603

D. Peter Hochberg Co., L.P.A.  
1940 E. 6<sup>th</sup> St. – 6<sup>th</sup> Floor  
Cleveland, OH 44114-2294  
(216) 771-3800